EXHIBIT R

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SILVERGATE PHARMACEUTICALS, INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. _____
	)	
ALKEM LABORATORIES LTD.,	)	
	)	
Defendant.	)	

COMPLAINT FOR PATENT INFRINGEMENT

For its Complaint against Defendant Alkem Laboratories Ltd. ("Alkem"), Plaintiff Silvergate Pharmaceuticals, Inc. ("Silvergate"), by and through its attorneys, alleges as follows:

THE NATURE OF THE ACTION

1. This is an action for patent infringement of United States Patent Nos. 9,669,008 ("the '008 patent"), 9,808,442 ("the '442 patent"), 10,039,745 ("the '745 patent"), and 10,154,987 ("the '987 patent") (collectively, the "Patents-in-Suit") under the patent laws of the United States of America, Title 35, United States Code, arising out of the submission by Alkem of Abbreviated New Drug Application ("ANDA") No. 213714 to the United States Food and Drug Administration ("FDA") seeking approval of a generic version of Silvergate's oral solution formulation that is the subject of New Drug Application ("NDA") No. 208686, hereinafter referred to as Silvergate's "Epaned® Product." Silvergate seeks all available relief under the patent laws of the United States, 35 U.S.C. § 100, *et seq.*, and other applicable laws for Alkem's infringement of the Patents-in-Suit.

THE PARTIES

2. Silvergate is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at 6251 Greenwood Plaza Blvd., Suite 101, Greenwood Village, CO 80111.

3. On information and belief, Alkem is an Indian corporation, having a principal place of business at Devashish Building, Alkem House, Senapti Bapat Road, Lower Parel, Mumbai – 400 013, India.

4. On information and belief, Alkem is in the business of, among other things, developing, manufacturing, marketing, importing, and selling generic copies of branded pharmaceutical products for the United States market.

JURISDICTION AND VENUE

5. This action arises under the patent laws of the United States of America, 35 U.S.C. § 100, *et seq.*, and from Alkem's submission of ANDA No. 213714 ("Alkem's ANDA").

6. This Court has subject matter jurisdiction over the action under 28 U.S.C. §§ 1331 and 1338(a). Relief is sought under 35 U.S.C. § 271(e)(2).

7. On information and belief, this Court has personal jurisdiction over Alkem because of, among other things, Alkem's persistent and continuous contacts with Delaware. Alkem has purposefully availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court here. On information and belief, Alkem regularly and continuously transacts business in Delaware, including by directly or indirectly developing, manufacturing, marketing, and selling generic pharmaceutical products in Delaware. On information and belief, Alkem derives substantial revenue from the sale of those products in Delaware, and has availed itself of the privilege of conducting business within

Delaware. Alkem regularly engaged in patent litigation concerning FDA-approved products in this judicial district, has not contested personal jurisdiction in such litigation in this judicial district, and has purposefully availed itself of the rights and benefits of this court by asserting claims and/or counterclaims in this Court. *See, e.g.*, *Boehringer Ingelheim Pharms. Inc. et al. v. Alkem Laboratories Ltd.*, C.A. No. 18-1738-CFC, D.I. 15 (D. Del. Jan. 11, 2019); *H. Lundbeck A/S et al. v. Alkem Labs. Ltd. et al.*, C.A. No. 18-89-LPS, D.I. 13 (D. Del. 2018 Apr. 2, 2018); *Biogen International GmbH et al. v. Alkem Labs. Ltd. et al.*, C.A. No. 17-850-LPS, D.I. 12 (D. Del. Oct. 16, 2017).

8. On information and belief, this judicial district is a likely destination of the product that is the subject of Alkem's ANDA.

9. Alternatively, this Court has personal jurisdiction over Alkem pursuant to Federal Rule of Civil Procedure 4(k)(2) because (a) Silvergate's claims arise under federal law; (b) Alkem is a foreign defendant not subject to personal jurisdiction in the courts of any state; and (c) Alkem has sufficient contacts with the United States as a whole, including, but not limited to, preparing and submitting ANDA No. 213714 to FDA and/or manufacturing, importing, offering to sell, and/or selling generic pharmaceutical products that are distributed throughout the United States, such that this Court's exercise of jurisdiction over Alkem satisfies due process.

10. Venue is proper in this Court under 28 U.S.C. §§ 1391(b) and (c) and 1400(b).

SILVERGATE'S EPANED® PRODUCT

11. Silvergate's Epaned® Product is the only FDA approved and labeled ace inhibitor treatment that is a ready-to-use oral solution for hypertension in children. Epaned® is also indicated to treat hypertension in adults, heart failure, and asymptomatic left ventricular dysfunction.

12. Silvergate holds approved NDA No. 208686 for its Epaned® Product.

PATENTS-IN-SUIT

13. The ’008 patent, entitled “Enalapril Formulations,” issued to Gerold Mosher and David Miles on June 6, 2017. A true and correct copy of the ’008 patent is attached to this Complaint as Exhibit A.

14. The ’008 patent was duly and legally issued to Silvergate as the assignee and Silvergate owns all rights, title, and interest in the ’008 patent.

15. Pursuant to 21 U.S.C. § 355, the ’008 patent is listed in the Approved Drug Products with Therapeutic Equivalence Evaluations (“the Orange Book”) in connection with Silvergate’s Epaned® Product.

16. Silvergate’s Epaned® Product is covered by at least one claim of the ’008 patent.

17. The ’442 patent, entitled “Enalapril Formulations,” issued to Gerold Mosher and David Miles on November 7, 2017. A true and correct copy of the ’442 patent is attached to this Complaint as Exhibit B.

18. The ’442 patent was duly and legally issued to Silvergate as the assignee and Silvergate owns all rights, title, and interest in the ’442 patent.

19. Pursuant to 21 U.S.C. § 355, the ’442 patent is listed in the Orange Book in connection with Silvergate’s Epaned® Product.

20. The use of Silvergate’s Epaned® Product is covered by at least one claim of the ’442 patent.

21. The approved indications for Silvergate’s Epaned® Product are covered by at least one claim of the ’442 patent.

22. The ’745 patent, entitled “Enalapril Formulations,” issued to Gerold Mosher and David Miles on August 7, 2018. A true and correct copy of the ’745 patent is attached to this Complaint as Exhibit C.

23. The ’745 patent was duly and legally issued to Silvergate as the assignee and Silvergate owns all rights, title, and interest in the ’745 patent.

24. Pursuant to 21 U.S.C. § 355, the ’745 patent is listed in the Orange Book in connection with Silvergate’s Epaned® Product.

25. Silvergate’s Epaned® Product is covered by at least one claim of the ’745 patent.

26. The ’987 patent, entitled “Enalapril Formulations,” issued to Gerold Mosher and David Miles on December 18, 2018. A true and correct copy of the ’987 patent is attached to this Complaint as Exhibit D.

27. The ’987 patent was duly and legally issued to Silvergate as the assignee and Silvergate owns all rights, title, and interest in the ’987 patent.

28. Pursuant to 21 U.S.C. § 355, the ’987 patent is listed in the Orange Book in connection with Silvergate’s Epaned® Product.

29. The use of Silvergate’s Epaned® Product is covered by at least one claim of the ’987 patent.

30. The approved indications for Silvergate’s Epaned® Product are covered by at least one claim of the ’987 patent.

INFRINGEMENT BY ALKEM

31. By letter dated September 23, 2019 (“Notice Letter”), and received by Silvergate on September 25, 2019, Alkem notified Silvergate that it had submitted ANDA No. 213714 to FDA under Section 505(j)(2)(B) of the Federal Food, Drug, and Cosmetic Act (“FDCA”) (21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95) seeking approval to engage in the commercial

manufacture, use, and sale of a generic version of Silvergate's Epaned® Product ("the Alkem ANDA Product") before the expiration of the Patents-in-Suit.

32. On information and belief, Alkem intends to engage in commercial manufacture, use, and sale of the Alkem ANDA Product promptly upon receiving FDA approval to do so.

33. By submitting ANDA No. 213714, Alkem has represented to FDA that the Alkem ANDA Product has the same active ingredients as Silvergate's Epaned® Product; has the same route of administration, dosage form, use, and strength as Silvergate's Epaned® Product; and is bioequivalent to Silvergate's Epaned® Product.

34. This action is being filed within forty-five (45) days of Silvergate's receipt of Alkem's Notice Letter.

CLAIMS FOR RELIEF

Count I—Infringement of the '008 patent

35. Silvergate incorporates each of the preceding paragraphs as if fully set forth herein.

36. Alkem submitted ANDA No. 213714 to FDA under section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Alkem ANDA Product throughout the United States before the expiration of the '008 patent. By submitting the ANDA, Alkem has committed an act of infringement of one or more claims of the '008 patent under 35 U.S.C. § 271(e).

37. If Alkem's ANDA is approved by FDA, the commercial manufacture, use, offer to sell, or sale within the United States, and/or importation into the United States of the Alkem ANDA Product will constitute acts of infringement of the '008 patent under 35 U.S.C. § 271(a)-(c) unless enjoined by the Court.

38. On information and belief, Alkem had actual and constructive knowledge of the '008 patent prior to submitting ANDA No. 213714 and was aware that submission of this ANDA to FDA constituted an act of infringement of the '008 patent. In addition, on information and belief, Alkem had specific intent to infringe the '008 patent when it filed ANDA No. 213714. Moreover, there are no substantial non-infringing uses for the Alkem ANDA Product other than as the pharmaceutical claimed in the '008 patent.

39. The commercial manufacture, use, offer for sale, sale, and/or importation of the Alkem ANDA Product in violation of Silvergate's patent rights will cause substantial and irreparable harm to Silvergate for which damages are inadequate.

Count II—Infringement of the '442 patent

40. Silvergate incorporates each of the preceding paragraphs as if fully set forth herein.

41. Alkem submitted ANDA No. 213714 to FDA under section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Alkem ANDA Product throughout the United States before the expiration of the '442 patent. By submitting the ANDA, Alkem has committed an act of infringement of one or more claims of the '442 patent under 35 U.S.C. § 271(e).

42. If Alkem's ANDA is approved by FDA, the commercial use, offer to sell, or sale within the United States, and/or importation into the United States of the Alkem ANDA Product will constitute acts of infringement of the '442 patent under 35 U.S.C. § 271(a)-(c) unless enjoined by the Court.

43. On information and belief, Alkem had actual and constructive knowledge of the '442 patent prior to submitting ANDA No. 213714 and was aware that submission of this ANDA to FDA constituted an act of infringement of the '442 patent. In addition, on information and

belief, Alkem had specific intent to infringe the ’442 patent when it filed ANDA No. 213714. Moreover, there are no substantial non-infringing uses for the Alkem ANDA Product other than the methods claimed in the ’442 patent.

44. The commercial use, offer for sale, sale, and/or importation of the Alkem ANDA Product in violation of Silvergate’s patent rights will cause substantial and irreparable harm to Silvergate for which damages are inadequate.

Count III—Infringement of the ’745 patent

45. Silvergate incorporates each of the preceding paragraphs as if fully set forth herein.

46. Alkem submitted ANDA No. 213714 to FDA under section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Alkem ANDA Product throughout the United States before the expiration of the ’745 patent. By submitting the ANDA, Alkem has committed an act of infringement of one or more claims of the ’745 patent under 35 U.S.C. § 271(e).

47. If Alkem’s ANDA is approved by FDA, the commercial manufacture, use, offer to sell, or sale within the United States, and/or importation into the United States of the Alkem ANDA Product will constitute acts of infringement of the ’745 patent under 35 U.S.C. § 271(a)-(c) unless enjoined by the Court.

48. On information and belief, Alkem had actual and constructive knowledge of the ’745 patent prior to submitting ANDA No. 213714 and was aware that submission of this ANDA to FDA constituted an act of infringement of the ’745 patent. In addition, on information and belief, Alkem had specific intent to infringe the ’745 patent when it filed ANDA No. 213714. Moreover, there are no substantial non-infringing uses for the Alkem ANDA Product other than as the pharmaceutical claimed in the ’745 patent.

49. The commercial manufacture, use, offer for sale, sale, and/or importation of the Alkem ANDA Product in violation of Silvergate's patent rights will cause substantial and irreparable harm to Silvergate for which damages are inadequate.

Count IV—Infringement of the '987 patent

50. Silvergate incorporates each of the preceding paragraphs as if fully set forth herein.

51. Alkem submitted ANDA No. 213714 to FDA under section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Alkem ANDA Product throughout the United States before the expiration of the '987 patent. By submitting the ANDA, Alkem has committed an act of infringement of one or more claims of the '987 patent under 35 U.S.C. § 271(e).

52. If Alkem's ANDA is approved by FDA, the commercial use, offer to sell, or sale within the United States, and/or importation into the United States of the Alkem ANDA Product will constitute acts of infringement of the '987 patent under 35 U.S.C. § 271(a)-(c) unless enjoined by the Court.

53. On information and belief, Alkem had actual and constructive knowledge of the '987 patent prior to submitting ANDA No. 213714 and was aware that submission of this ANDA to FDA constituted an act of infringement of the '987 patent. In addition, on information and belief, Alkem had specific intent to infringe the '987 patent when it filed ANDA No. 213714. Moreover, there are no substantial non-infringing uses for the Alkem ANDA Product other than the methods claimed in the '987 patent.

54. The commercial use, offer for sale, sale, and/or importation of the Alkem ANDA Product in violation of Silvergate's patent rights will cause substantial and irreparable harm to Silvergate for which damages are inadequate.

PRAYER FOR RELIEF

Silvergate respectfully requests the following relief:

a) A judgment that Alkem has infringed the '008 patent, the '442 patent, the '745 patent, and the '987 patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 213714 under Section 505(j) of the FDCA, and that Alkem's making, using, offering to sell, or selling in the United States or importing into the United States of the Alkem ANDA Product will infringe one or more claims of the '008 patent, the '442 patent, the'745 patent, and the'987 patent;

b) A finding that the '008 patent, the '442 patent, the '745 patent, and the '987 patent are valid and enforceable;

c) An order under 35 U.S.C. § 271(e)(4)(A) that the effective date of any FDA approval of ANDA No. 213714 shall be a date which is not earlier than the latest expiration date of the '008 patent, the '442 patent, the '745 patent, and the '987 patent, as extended by any applicable periods of exclusivity;

d) An order under 35 U.S.C. § 27l(e)(4)(B) permanently enjoining Alkem, its subsidiaries, parents, officers, agents, servants, employees, licensees, representatives, and attorneys, and all other persons acting or attempting to act in active concert or participation with it or acting on its behalf, from engaging in the commercial manufacture, use, offer to sell, sale, or importation into the United States, of any drug product the use of which is covered by the '008 patent, the '442 patent, the '745 patent, and the '987 patent, including the Alkem ANDA Product;

e) A finding that this is an exceptional case under 35 U.S.C. § 285, and that Silvergate be awarded reasonable attorneys' fees and costs; and

f) An award of any such other and further relief as the Court may deem just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

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